NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading since the article was not capable of accomplishing the results stated and implied by such statements. The statements represented and suggested that calves would seldom scour when the article was fed to them; that the article would insure healthy litters from sows; that it would help reduce baby chick fatalities; that by adding the article to the dairy ration, dairy cows would have a higher disease resistance and would be in better condition to assimilate their feed and turn it into butterfat and milk production; and that the article would tend to keep sows healthy and insure a good flow of milk when they farrow.

DISPOSITION: June 15, 1950. Default decree of condemnation and destruction.

3200. Adulteration and misbranding of Spear egg mash. U. S. v. 15 Bags, etc. (F. D. C. No. 29095. Sample Nos. 70959–K, 70960–K.)

LIBEL FILED: May 5, 1950, District of Kansas.

ALLEGED SHIPMENT: On or about March 16, 1950, by Spear Mills, Inc., from Kansas City, Mo.

PRODUCT: 32 bags of Spear egg mash at Kansas City, Kans. Examination showed that the product contained not more than 127 grains of nicotine and not more than 563 grains of phenothiazine per 100 pounds.

LABEL, IN PART: "Spear Egg Mash [or "Spear 'All Mash' Egg Mash"] with Worm Control for Large Round Worms and Cecal Worms Active Ingredients: Nicotine as Alkaloid 175 grains and Phenothiazine 600 grains per 100 lbs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, "Nicotine as Alkaloid 175 grains and Phenothiazine 600 grains per 100 lbs."

Misbranding, Section 502 (a), the statements "Egg Mash with Worm Control for Large Round Worms and Cecal Worms * * * it has the Spear Worm Control Formula built-in the feed as an effective treatment against large round worms and cecal worms," appearing on the tag attached to the bags, were false and misleading since the article when used as directed, namely, "It is to be fed 5 consecutive days each month in place of regular Spear * * Feeds. It is not necessary to feed this special feed more than 5 days each month," would not constitute an effective control or treatment of large round worm and cecal worm infestation of poultry.

DISPOSITION: June 24, 1950. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3181 TO 3200 PRODUCTS

N. J. No.		J. No.
	Celery Fruit (celery seed), Fluid	,
Amberin 23193	Extract No. 118; and Celery	
Antihistamine tablets 3183	Compound, Green's	3188
Arthritis, remedies for 3187, 3188	Creme-A-Tone	3191
Breed 3199 Calcium fluoride tablets, calcium	Devices 3192,	3197
phosphate tablets, and cal-	Egg mash, Spear	3200
cium sulfate tablets 3196	Elgyn capsules	3191

^{1 (3190)} Permanent injunction issued.

^{3 (3193)} Prosecution contested.

Issued January 1953

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 765 of the Food, Drug, and Cosmetic Act]

3201-3220

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, Commissioner of Food and Drugs.

WASHINGTON, D. C., January 2, 1951

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Drugs actionable because of potential danger when used according to directions. Drugs actionable because of failure to bear adequate directions or warning statements. Drugs and devices actionable because of deviation from official		Drugs for human use Drugs for veterinary use	196 196 201
or own standards	195		

^{*}For presence of a habit-forming narcotic without warning statement, see Nos. 3202, 3204-3206; omission of, or unsatisfactory, ingredients statements, Nos. 3202, 3203, 3207, 3211, 3213, 3219; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3202-3207; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3202, 3204-3207; cosmetic, actionable under the drug provisions of the Act, No. 3215.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3201. Misbranding of procaine hydrochloride 2% and adulteration and misbranding of Salicyline No. 2 tablets. U. S. v. C. B. Kendall Co., Inc., Claude B. Kendall, and Ralph E. Monteith. Pleas of nolo contendere. Fines of \$1,800 against corporation, \$1,800 against defendant Monteith, and \$900 against defendant Kendall. (F. D. C. No. 28097. Sample Nos. 23084-K, 23086-K, 23441-K, 23774-K, 23776-K, 23778-K, 23973-K, 43464-K, 43465-K.)

INDICTMENT RETURNED: On or about March 13, 1950, Southern District of Indiana, against C. B. Kendall Co., Inc., Indianapolis, Ind., Claude B. Kendall, president of the corporation, and Ralph E. Monteith, chief chemist for the corporation.

ALLEGED SHIPMENT: Between the approximate dates of February 23, 1948, and January 20, 1949, from the State of Indiana into the States of Louisiana, Texas, and Illinois.

LABEL, IN PART: "Procaine Hydrochloride 2% Kendall" and "Tablets Salicyline No. 2 * * * Kendall."

NATURE OF CHARGE: Procaine hydrochloride 2%. Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, "Average Dose: As required, inject subcutaneous or intradermal" and "Average Dose: As required, subcutaneous or intradermal," since such use of the article in such dosage and frequency may result in destruction of body tissue because of the acidity of the article.

Salicyline No. 2 tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet was represented to contain 5,000 units of vitamin D, whereas each tablet contained less than 5,000 units of vitamin D. Misbranding, Section 502 (a), the label statement "Each tablet contains: * * * Vitamin D 5,000 units" was false and misleading.

DISPOSITION: On May 26, 1950, pleas of nolo contendere were entered on behalf of each of the defendants, and on July 14, 1950, after consideration of the written statements and oral comments of counsel, the court found the defendants guilty as charged and imposed the fines hereinbefore reported. In sentencing the defendants, the court made the following statement:

STECKLER, District Judge: "This case has certainly given the Court a great deal of concern, not by reason of the particular facts in this case, but in addition to that, this seems to be the home of some of the largest pharmaceutical manufacturers in the world. It is my understanding that this city is beginning to be known somewhat as a pharmaceutical city, along with Philadelphia and a few other large cities.

"I fully realize that the company, without penalty of the Court, will be seriously injured by reason of the civil actions which no doubt will be brought, claims that will be made. On the other hand, the Court can't lose sight of the fact that any company that is engaged in the drug business is under the strictest duty to maintain the integrity of that industry. The public has no way at all of protecting itself against the use of harmful drugs, if they are harmful, particularly when they are given under the prescription of the doctor, or injected by a doctor. Usually, I would say, the doctor in those circumstances would be innocent, too, if something was wrong with the drug.

"The penalty in a case like this, as far as punishing the corporation, would be, primarily, to serve as a reminder ever in the future to exercise the strictest policies in respect to the work of the personnel in reference to their particular